REMARKS

I. Status of the Application

This Amendment is submitted in response to the Office Action mailed February 3, 2012 in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on May 3, 2012. Accordingly, this Amendment is timely submitted.

Claims 1, 3-5, 11, 13, 17-19, 29, 37, 47, 56-58, 60-63, 67-68, and 71-72 are pending in the application. Claim 7 is cancelled. Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 47, 56-58, 60-63, 67-68, and 71-72 are rejected. Claims 1, 3, 5, 37, 60, 71, and 72 have been amended in order to further clarify the invention or the claims. Support for these amendments can be found at least in Tables 2 and 5, and claim 2 of the published specification. As such, no new matter is entered, and entry of the amendments and reconsideration of the pending claims is requested.

II. Claim Objections

Claims 71 and 72 are objected to for the alleged recitation of superfluous limitations. In response, claims 71 and 72 have been amended to remove the alleged superfluous recitations. As such, reconsideration of the objection over claims 71 and 72 is respectfully requested.

Claim 60 is objected to for the use of the term "or" in the phrase "an antioxidant, or an emollient." In response, claim 60 has been amended to replace "or" with the word "and" as suggested by the Examiner. As such, reconsideration of the objection over claim 60 is respectfully requested.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67-68, and 71-72 are rejected under 35 U.S.C. § 112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the phrase "long-chain" fatty acid is allegedly indefinite.

The Applicants traverse the rejection. The term "long-chain" fatty acid is an art recognized term, as evidence by Bruzzese and Agnosti, 1992, submitted herewith as Exhibit A. As can be seen, a "long-chain" fatty acid is an art recognized as having 14 carbons or longer in

the main chain. As such, reconsideration and withdrawal of the rejection over claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67-68, and 71-72 is respectfully requested.

Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67-68, and 71-72 are rejected under 35 U.S.C. § 112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Office Action alleges that percentages recited within the claims do not specify whether they are associated with the weight of the formulation or of the delivery vehicle. As such, the claims are allegedly rendered indefinite.

The Applicants traverse the rejection. However, in order to advance prosecution, claims 1, 37, 60, 71, and 72 have been amended. Claims 1, 37, 60, 71, and 72 have been amended to include the phrase "in the formulation" as appropriate. Support for these amendments can be found in Tables 1 and 2 of the published specification. Claims 3-5, 11, 13, 17-19, 29, 37, 46, 56-58, 61-63, and 67-68 depend from amended claims 1, 37 or 60. As such, reconsideration and withdrawal of the rejection over claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67-68, and 71-72 is respectfully requested.

Claims 3 and 7 are rejected under 35 U.S.C. § 112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Office Action alleges that there is insufficient basis for the terms "alkanol," "polyalcohol," and "permeation enhancer" in claim 1. As such, the claims are allegedly rendered indefinite.

In response, claim 3 has been amended in order to clarify the claim, and claim 7 is cancelled herein. As such, reconsideration and withdrawal of the rejection over claims 3 and 7 is respectfully requested.

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Office Action alleges that there is insufficient basis for the terms "alkanol" in claim 1. Further, the Office Action alleges that it is unclear how ethanol is present at 47.5% by weight of the delivery vehicle and can also be present at 5-80% of the hydroalcoholic mixture. Additionally, the Office Action alleges that it is unclear how water is included in the delivery vehicle within claim 5, but not included in the delivery vehicle as recited in claim 1. As such, the claim is allegedly rendered indefinite.

In response, claim 1 and claim 5 have been amended in order to clarify the claims. With regard to the lack of antecedent basis of the term "alkanol" recited in claim 5 but not claim 1, the term has been deleted from claim 5 and replaced with the term "ethanol" for consistency.

With regard to the alleged indefiniteness of the specific percentages of ethanol in the delivery vehicle and the hydroalcoholic mixture, the claims are not unclear. As the delivery vehicle is only a percentage of the total formulation, the hydroalcoholic mixture too is only a percentage of the total delivery vehicle. Further, claim 1 has been amended such that water is included in the delivery vehicle. Specific support for this amendment can be found at least at paragraphs [0019] and [0049] of the specification. As such, reconsideration and withdrawal of the rejection over claim 5 is respectfully requested.

Claim 72 is rejected under 35 U.S.C. §112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Office Action alleges that there is insufficient basis for the term "polyalchohol" in claim 60. As such, the claim is allegedly rendered indefinite.

In response, the term "polyalcohol" recited in claim 72 has been deleted in order to clarify the claim. As such, reconsideration and withdrawal of the rejection over claim 72 is respectfully requested.

Claims 37 and 60 are rejected under 35 U.S.C. § 112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Office Action alleges that there use of the term "comprising" in the body of the claim after the transitional phrase "consisting essentially of" or "consisting of" renders the claim indefinite.

In response, claims 37 and 60 have been amended to replace the term "comprising" with the term "including" in order to clarify the claims. As such, reconsideration and withdrawal of the rejection over claims 37 and 60 is respectfully requested.

IV. Rejections Under 35 U.S.C. § 112, Fourth Paragraph

Claim 5 is rejected under 35 U.S.C. § 112, fourth paragraph as failing to further limit the claim upon which it depends.

The Applicants traverse the rejection. However, in order to advance prosecution, claims 1 and 5 have been amended in order to clarify the claims. As explained above, the delivery

vehicle is only a percentage of the total formulation, the hydroalcoholic mixture too is only a percentage of the total delivery vehicle. As amended, claim 1 requires that ethanol is present in an amount of 47.5% of the formulation. Claim 5 requires that the hydroalcoholic mixture is present in an amount of 40-98% of the delivery vehicle, and the ethanol is present in an amount of between 5-80% of the hydroalcoholic mixture. Further, claim 1 has been amended such that water is included in the delivery vehicle.

As such, reconsideration and withdrawal of the rejection over claim 5 is respectfully requested.

Claim 7 is rejected under 35 U.S.C. § 112, fourth paragraph as failing to further limit the claim upon which it depends. Claim 7 is cancelled herein to render the rejection moot.

V. Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3-5, 7, 11, 13, 29, 37, 46, 56-58, 60-63, 67, 68, 71, and 72 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over WO 02/22132 to "Gray" in view of U.S. Patent No. 6,503,894 to "Dudley" and Wang et al, The Journal of Clinical Endocrinology and Metabolism, 2000, hereinafter "Wang." The Office Action alleges that Gray discloses a topical hormonal composition, but fails to disclose testosterone or a kit that includes a pump. The Office Action attempts to cure the deficiencies of Gray with the disclosure of Dudley or Wang.

Independent claims 1, 37 and 60 require formulations consisting essentially of, or consisting of, at least 1) a single active agent of testosterone; 2) a delivery vehicle including at least ethanol, polyethylene glycol, a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through a mammalian dermal or mucosal surface, and water, wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids, and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during the use of the formulation and the delivery vehicle facilitates absorption of at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

Gray discloses a topical hormonal composition that "comprises, as active ingredients, a progestogen…and estradiol" in a vehicle which allows the systemic passage of the active agents. See, Abstract. Gray describes that the active ingredients themselves can affect the passage of the active ingredients (see, Column 11, lines 3-54), and more specifically that the estradiol promotes

the diffusion of nomegestrol acetate, and that nomedgestrol acetate slows the diffusion of estradiol (column 12, lines 43-56). Additionally, Gray discloses, surprisingly, that the excipients used within the formulations can also affect the diffusion of the active ingredients, and can in fact slow their diffusion (column 16, lines 6-10), thus providing a material effect on the formulation.

Dudley discloses a composition comprising 1% testosterone, ethanol, isopropyl myristate *(a long chain fatty acid),* and water that is used to treat hypogonadism (see Abstract). The tradename for the composition is AndroGel ™. Dudley describes that its compositions are capable of overcoming problems associated with known testosterone delivery compositions, including transdermal patches, oral/sublingual/buccal preparations and implants. Dudley discloses extensive studies showing the efficacy of the compositions disclosed therein in comparison to other testosterone formulations available (see Examples and Figures).

Wang discloses a 1% by weight testosterone gel (AndroGel ™) dispensed in multidose bottles with an actuator pump.

Contrary to the allegation that it would have been "well within the purview of one or ordinary skill in the art to use the appropriate hormone, such as testosterone at 1 wt% in the formulations of Gray et al " (see Office Action page 12) and "it is apparent to one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention" (see, Office Action page 13), the Applicants do not agree.

First, Gray does not describe the ability to utilize its formulations for alternate treating agents. In fact, as described above, the success of the formulations in allowing sufficient passage of the treating agents requires both a progestogen and estradiol. Thus, a skilled artisan would not simply exchange both the progestogen and the estradiol with the testosterone from Dudley and/or Wang and expect that the formulations would be able to successfully transmit testosterone through the skin.

Secondly, the pending claims require that the compositions "consist essentially of" or "consist of" 1% testosterone and the delivery vehicle that is essentially free of long chain fatty acids, long chain fatty alcohols, and long chain fatty esters. The amendments and pending claims closely follow specific preparations disclosed in Tables 2 and 5 of the published specification. The addition of other treating agents and excipients required in the formulations of Gray -- which are disclosed as affecting the transmission of the active agents of Gray -- are

excluded from the pending claims, and would materially affect the basic and novel characteristics of the presently claimed invention.

Thirdly, Wang fails to cure the deficiency of either Gray or Dudley over claims 1, 37 and 60. Wang merely discloses AndroGel ^{TM} in a bottle with an actuator pump.

Thus, a skilled artisan would not be motivated to arrive at the claimed invention from the disclosure of Gray, Dudley or Wang. Gray's formulations utilize two treating agents which are outside the scope of the instant claims, and Gray shows that the treating agents affect their own transmission, and that surprisingly, even known excipients affect the transmission of the treating agents. Additionally, Dudley utilizes 1% testosterone formulations utilizing long-chain fatty acids which are outside of the pending claims, and which Dudley discloses as over-coming problems with known testosterone transmitting formulations. Wang merely utilizes the same testosterone formulation as Dudley. A skilled artisan would not be motivated to modify Gray, because Gray clearly shows the success of its formulations affect transmission of the active agents; and a skilled artisan would not be motivated to modify Dudley because Dudley already has overcome the known problems in the art at the time of the invention.

Thus, neither Gray, Dudley nor Wang, alone or in combination, results in independent claims 1, 37 and 60. Because claims 3-5, 11, 13, 29, 46, 56-58, 61-63, 67, 68, 71, and 72 are all ultimately dependent upon claims 1, 37 and 60, these claims are allowable for the same reasons. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 17-19 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Gray, Dudley, and Wang further in view of Shifren, Davids, and Sherwin.

The Applicants traverse the rejection. Claims 17-19 ultimately depend from allowable claim 1, and are allowable for the same reasons. Thus, reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection is requested.

VI. Double Patenting Rejections

Claims 1, 3-5, 7, 11, 13, 17-19, 37, 46, 56-58, 60-63, 67, 68, 71, and 72 are rejected on the ground of nonstatutory obviousness-type double patent as being unpatentable over claims 1, 5-10, 12, 13, 16, and 18 of U.S. Patent No. 6,503,894. In response, a suitable disclaimer is enclosed in order to vitiate this rejection.

Claims 1, 3-5, 7, 11, 13, 17-19, 37, 46, 56-58, 60-63, 67, 68, 71, and 72 are rejected on the ground of nonstatutory obviousness-type double patent as being unpatentable over claims 1-13 of U.S. Patent No. 8,067,399. In response, a suitable disclaimer is enclosed in order to vitiate this rejection.

Claims 1, 3-5, 7, 11, 13, 17-19, 37, 46, 56-58, 60-63, 67, 68, 71, and 72 are provisionally rejected on the ground of nonstatutory obviousness-type double patent as being unpatentable over claims 1-9 and 16-22 of copending U.S. Patent Application No. 13/044,447. In response, a suitable disclaimer is enclosed in order to vitiate this rejection.

Claims 1, 3-5, 7, 11, 13, 17-19, 37, 46, 56-58, 60-63, 67, 68, 71, and 72 are provisionally rejected on the ground of nonstatutory obviousness-type double patent as being unpatentable over claims 1-5 of copending U.S. Patent Application No. 13/106,715. In response, a suitable disclaimer is enclosed in order to vitiate this rejection.

Conclusion

It is believed that the entire application is now in condition for allowance, early notice of which would be appreciated. If any issues remain that can be overcome most easily through a telephone communication, the Examiner is invited to telephone the undersigned at the telephone number set forth below.

Respectfully submitted,

Date: April 2, 2012

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EXHIBIT A

Pediatr Med Chir. 1992 Sep-Oct;14(5):473-9.

[Fatty acids: their biochemical and functional classification].

[Article in Italian]

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Abstract

Fatty acids (FA) constitute the main component of phospholipids, triglycerides and cholesterol esters. FA are acidic, monocarboxylic linear chains of variable length: **short-chain** FA (2-4 **carbon** atoms), **medium-chain** FA (6-12 **carbon** atoms), **long-chain** FA (14-18 **carbon** atoms), very **long-chain** FA (derived from parental 18-**carbon** molecules). They can be further subdivided into saturated (no double bond), monounsaturated (one double bond) and polyunsaturated (two or more double bonds). They are all involved in energetic, metabolic and structural activities. **Short-chain** FA act as growth factors; **medium chain** FA are readily available as energy source; saturated **long-chain** FA constitute a source of energy but may be implicated in the development of the atherosclerotic process; unsaturated **long-chain** FA include oleic **acid** and the essential **fatty acids** (linoleate and linolenate), and are all implicated in fundamental metabolic processes; very-**long chain** FA are the most characteristic molecules in biologic membranes. From recent works it is clearly established that the physiological role of FA depends on the **chain** length, and that the very-**long chain** molecules could determine the quality of human development. A functional classification of FA today must be based not only on the rate of unsaturation, but also (and most importantly) on the **chain** length.

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